



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,902

12/22/99

CRAIG

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F31251C1

020462

HM12/1201

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EXAMINER

CHANG, C

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

12/01/00

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/469,902

Applicant(s)

CRAIG ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 40-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 40-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. This application has been withdrawn from issuance by the notification in Paper No. 4, dated August 21, 2000.

Rejections

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Benneker et al. US 5,874,447, (cited on 1449) see claims 27-29 and column 9, lines 45-50. It is noted that the IR band width may vary with measuring condition. The standard error (see $\pm 4\text{cm}^{-1}$) of the claims placed the IR bands within the same proximity as the Benneker et al. product. In the event that the discrepancy between the IR peak values and those disclosed by Benneker et al. are the results of employing different equipment, solvents, measuring conditions etc. then, the product of the claim and the product disclosed by Benneker '447 are identical.

In addition, it is noted that the Benneker et al. methanesulfonate is crystalline because it was crystallized by seeding crystal, and the melting point of the methanesulfonate is 145.8°C (see col. 9, line 48), which is within measurement error of the claims of 146°C.

Anticipation is found.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benneker et al, '447 in view of Jacswicz GB 2,297,550 (cited on 1449).

Determination of the scope and content of the prior art (MPEP §2141.01)

Benneker et al. '447 disclosed purified paroxetine methanesulfonate in crystalline form (see example 1, col. 7, with seeding crystal at line 52). A pharmaceutical composition is also disclosed and claimed as claims 21-26.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Benneker et al. '447 disclosed all the elements of the claims **except** that the instant claims and the Benneker '447 disclosure have different IR bands. Jacswicz '550 taught that paroxetine salts exist in polymorphs and polymorphs of the same product have different IR bands (see whole article including forms A-D and IR spectrums). Therefore, the difference in IR bands merely represent a different form of a known/conventional product.

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be motivated to employ an alternative form which have an IR bands representing a different form of an old product, in a pharmaceutical preparation of the old form knowing that the new form differ from the old form merely in measurable physical parameter with no difference in the chemical nature of the products or its therapeutical property i.e. same elemental/chemical component.

In absence of unexpected results, there is nothing unobvious in choosing an alternative new form to be used for the very same utility of the known form.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes et al. US 4,721,723 (cited on 1449). See Barnes '723 column 7, example 3 and instant specification p.51-52. Please note that the hydrochloride salt prepared by the process are hemihydrate which have the same IR as the known hemihydrate

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(p.51 line 22). The product of the claims, therefore, is identical to the prior art product and anticipation is found.

5. Claims 41, 43, 45, 47, 49, 51, 53, 55, 57, 59, 61, 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 4,721,723; or claims 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,063,927; or claims 40-63 are provisionally rejected over the pending claims or the copending application SN 09/454,881.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to the same paroxetine hydrochloride hemihydrate prepared with alternative process as the '723 claims, or the instant claims are drawn to the same or new form of the same methanesulfonate of the claims of US 6,063,927. The method of using an alternative form of the conventional product for the very same utility known for the old form is prima facie obvious since the new form differ from the old form merely in physical parameter without change in chemical/biological activity.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CCPC/Chang
Nov. 27, 2000



CEILA CHANG
PRIMARY EXAMINER
GROUP 1200 / 1625